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Paper No.

LAHIVE & COCKFIELD, LLP FLOOR 30, SUITE 3000 ONE POST OFFICE SQUARE BOSTON MA 02109

MAILED

AUG 1 8 2010

PATENT TERM ADJUSTMENT

OFFICE OF PETITIONS

LETTER REGARDING

In re Application of

Boivin et al.

Application No. 10/507,067

Filed: November 10, 2004

Docket No. EISN-018US

Title: MACROCYCLIC COMPOUNDS USEFUL

AS PHARMACEUTICALS

This is in response to the "APPLICATION FOR PATNET TERM ADJUSTMENT UNDER 37 CFR §1.705(b)," filed July 15, 2010. Applicants request that the determination of patent term adjustment be increased by nine hundred and seventy-four (974) days to one thousand, two hundred and sixty-five (1265) days as calculated by the Office as of the mailing of the initial determination of patent term adjustment. Applicants request this correction partly on the basis that the Office will take in excess of three years to issue this patent. In addition, Applicants contend that one period of Office delay was incorrectly assigned and one period of applicant delay was incorrectly omitted.

To the extent that the instant application for patent term adjustment requests reconsideration of the patent term adjustment as it relates to the Office's failure to issue the patent within 3 years of the filing date, the application for patent term adjustment under 37 CFR 1.'705(b) is DISMISSED as PREMATURE.

Knowledge of the actual date the patent issues is required to calculate the amount, if any, of additional patent term patentee is entitled to for Office failure to issue the patent within 3 years. See § 1.702(b). (This is true even where a request for continued examination (RCE) was filed). The computer will not undertake the § 1.702(b) calculation until the actual date of

issuance of the patent has been determined. Likewise, the computer will not calculate any further Office delay under § 1.702(a)(4) or applicant delay under § 1.704(c)(10) until the actual date of issuance of the patent has been determined. As such, the Office can not make a determination on the correctness of the patent term adjustment until the patent has issued.

Requesting reconsideration of the patent term adjustment to be indicated on the patent under 37 CFR 1.705(b) based on the initial determination of patent term adjustment and a projected issuance date of the patent (or even the filing date of the request for continued examination) is premature. Accordingly, it is appropriate to dismiss as premature such a request.

Rather than file an application for patent term adjustment under 37 CFR 1.705(b) contesting the 37 CFR 1.702(b) calculation at the time of the mailing of the notice of allowance, Applicants are advised that they may wait until the time of the issuance of the patent and file a request for reconsideration of the patent term adjustment pursuant to 37 CFR 1.705(d). As the USPTO does not calculate the amount of time earned pursuant to 37 CFR 1.702(b) until the time of the issuance of the patent, the Office will consider any request for reconsideration of the patent term adjustment due to an error in the calculation of 37 CFR 1.702(b) to be timely if the request for reconsideration is filed within two months of the issuance of the patent. as to all other bases for contesting the initial determination of patent term adjustment received with the notice of allowance, applicant must timely file an application for patent term adjustment prior to the payment of the issue fee1.

To the extent that Applicants otherwise request reconsideration of the patent term adjustment at the time of the mailing of the notice of allowance, the request is **GRANTED**.

For example, if applicant disputes both the calculation of patent term adjustment under 37 CFR 1.702(a)(1) for Office failure to mail a first Office action or notice of allowance not later than fourteen months after the date on which the application was filed and under 37 CFR 1.702(b) for Office failure to issue a patent within three years of the actual filing date of the application, then applicant must still timely file an application for patent term adjustment prior to the payment of the issue fee to contest the calculation of Office delay in issuing a first Office action or notice of allowance. See 37 CFR 1.705(b) and 35 U.S.C. 154(b)(3)(B). A dispute as to the calculation of the §1.702(a)(1) period raised on request for reconsideration of patent term adjustment under 37 CFR 1.705(d) will be dismissed as untimely filed.

Applicants dispute the adjustment of 51 days, pursuant to 37 CFR 1.703(a)(3) for Office delay in mailing a notice of allowance in response to the submission of a reply in compliance with 37 C.F.R. § 1.113(c): a first after-final amendment was filed on October 23, 2009, an advisory action was mailed on November 6, 2009, a second after-final amendment was filed on November 13, 2009, a third after-final amendment was filed on February 17, 2010, and a notice of allowance was mailed on April 15, 2010.

Applicants maintain that the Office incorrectly calculated the 4-month period for response as commencing on the 4-month anniversary of the October 23, 2009 amendment, instead of the 4-month anniversary of the February 17, 2010 amendment (which was in compliance with 37 C.F.R. § 1.113(c).

Applicants further dispute the failure to accord a reduction of 118 days, pursuant to 37 CFR 1.704(c)(7) for applicant delay in filing a reply which contains an omission: a non-final Office action was mailed on August 16, 2007, a reply was submitted on February 19, 2008, a notice of non-compliant amendment was mailed on May 14, 2008, and a reply correcting the omission was provided on June 16, 2008, 118 days after the submission of February 19, 2008.

Applicants maintain that 118 days of applicant delay should have been accorded.

Applicants state that any patent issuing from the application is not subject to a terminal disclaimer.²

The application history has been reviewed and it has been determined that Applicants are correct on both counts.

With regard to the adjustment of 51 days, the Office agrees that it was improper to have calculated the 4-month period for response required by 37 CFR 1.703(a)(3) as commencing with the 4-month anniversary of the October 23, 2009 after-final amendment: the Office should have calculated the period for response as commencing with the 4-month anniversary of the February 17, 2010 amendment. As such, the notice of allowance was timely mailed, and no adjustment should have been made.

The adjustment of 51 days has been removed.

² Petition, page 5.

With regard to the submission of a reply which contains an omission, the Office agrees that a 118-day reduction should have been accorded.

A reduction of 118 days has been entered.

In view thereof, the patent term adjustment at the time of the mailing of the notice of allowance is one hundred and twenty-two (122) days (476 days of Office delay minus 354 days of Applicant delay).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

The Office thanks Applicants for their good faith and candor in bringing this to the attention of the Office.

Applicants are reminded that any delays by the Office pursuant to 37 CFR 1.702(a)(4) and 1.702(b) and any applicant delays under 37 CFR 1.704(c)(10) will be calculated at the time of the issuance of the patent and applicants will be notified of the revised patent term adjustment to be indicated on the patent in the Issue Notification letter that is mailed to Applicants approximately three weeks prior to issuance.

The Office of Data Management has been advised of this decision. This matter is being referred to the Office of Data Management for issuance of the patent.

Telephone inquiries regarding this matter should be directed to Senior Attorney Paul Shanoski at (571) 272-3225.

Anthony Knight

Director

Office of Petitions

Enclosure: Copy of updated PAIR screen

Day : Tuesday Date: 8/17/2010



PALM INTRANET

Time: 15:22:37

PTA Calculations for Application: 10/507067					
Application Filing Date: 11/10/2004	PTO Delay (PTO): 527				
Issue Date of Patent:	Three Years: 0				
Pre-Issue Petitions: 0	Applicant Delay (APPL): 236	,			
Post-Issue Petitions: 0	Total PTA (days): 122	?			
PTO Delay Adjustment: -169					

	File Contents History						
Number	Date	Contents Description	PTO	APPL	START		
91	08/17/2010	ADJUSTMENT OF PTA CALCULATION BY PTO		102			
90	08/17/2010	ADJUSTMENT OF PTA CALCULATION BY PTO		118			
89	08/17/2010	ADJUSTMENT OF PTA CALCULATION BY PTO	51				
80	04/15/2010	MAIL NOTICE OF ALLOWANCE	51		57		
79	04/12/2010	ISSUE REVISION COMPLETED					
78	04/12/2010	DOCUMENT VERIFICATION					
77	04/12/2010	NOTICE OF ALLOWANCE DATA VERIFICATION COMPLETED					
76	04/12/2010	CASE DOCKETED TO EXAMINER IN GAU					
75	04/08/2010	EXAMINER'S AMENDMENT COMMUNICATION					
74	04/08/2010	NOTICE OF ALLOWABILITY			,		
70	10/23/2009	INFORMATION DISCLOSURE STATEMENT CONSIDERED					
69	10/23/2009	INFORMATION DISCLOSURE STATEMENT CONSIDERED					
68	03/31/2010	DATE FORWARDED TO EXAMINER					
67	02/17/2010	AMENDMENT/ARGUMENT AFTER NOTICE OF APPEAL		,			
64		NOTICE OF APPEAL FILED					
63	12/18/2009	REQUEST FOR EXTENSION OF TIME - GRANTED					
62	11/20/2009	DATE FORWARDED TO EXAMINER					
61	11/13/2009	SUPPLEMENTAL RESPONSE		21	57		
60	11/06/2009	MAIL ADVISORY ACTION (PTOL - 303)					
59	11/05/2009	ADVISORY ACTION (PTOL-303)					
58	10/27/2009	DATE FORWARDED TO EXAMINER					
57	10/23/2009	AMENDMENT AFTER FINAL REJECTION		30	51		

56	10/23/2009	REQUEST FOR EXTENSION OF TIME - GRANTED		
55	10/23/2009	INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
54	10/23/2009	INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
53	10/23/2009	INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
52	10/23/2009	INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
51	06/23/2009	MAIL FINAL REJECTION (PTOL - 326)		
50	06/18/2009	FINAL REJECTION		
49	03/10/2009	INFORMATION DISCLOSURE STATEMENT CONSIDERED		
48	03/10/2009	INFORMATION DISCLOSURE STATEMENT (IDS) FILED	0	46
47	04/08/2009	DATE FORWARDED TO EXAMINER		
46		RESPONSE AFTER NON-FINAL ACTION	90	43
45	03/10/2009	REQUEST FOR EXTENSION OF TIME - GRANTED		
44	03/10/2009	INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
43	09/10/2008	MAIL NON-FINAL REJECTION		
42	09/09/2008	NON-FINAL REJECTION		
41	07/02/2008	DATE FORWARDED TO EXAMINER		
40	06/16/2008	RESPONSE AFTER NON-FINAL ACTION		
39	05/14/2008	MAIL MISCELLANEOUS COMMUNICATION TO APPLICANT		
38		MISCELLANEOUS ACTION WITH SSP		
37	02/26/2008	OATH OR DECLARATION FILED (INCLUDING SUPPLEMENTAL)		
- 36	02/26/2008	OATH OR DECLARATION FILED (INCLUDING SUPPLEMENTAL)		
35	02/26/2008	MISCELLANEOUS INCOMING LETTER		
34	03/10/2008	DATE FORWARDED TO EXAMINER		
33	02/19/2008	RESPONSE AFTER NON-FINAL ACTION	95	30
32	02/19/2008	REQUEST FOR EXTENSION OF TIME - GRANTED		
31	02/08/2008	CORRESPONDENCE ADDRESS CHANGE		
30	08/16/2007	MAIL NON-FINAL REJECTION		
29	08/03/2007	NON-FINAL REJECTION		

28	11/10/2004	INFORMATION DISCLOSURE STATEMENT CONSIDERED		
27	05/25/2006	INFORMATION DISCLOSURE STATEMENT CONSIDERED		
26		DATE FORWARDED TO EXAMINER		
25	06/01/2007	RESPONSE TO ELECTION / RESTRICTION FILED		
24	05/08/2007	MISCELLANEOUS INCOMING LETTER		
23	05/01/2007	MAIL RESTRICTION REQUIREMENT	476	9
22	04/30/2007	REQUIREMENT FOR RESTRICTION / ELECTION		
21	03/12/2007	CASE DOCKETED TO EXAMINER IN GAU		
20.7	05/25/2006	INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
20	05/25/2006	INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
19	03/27/2006	IFW TSS PROCESSING BY TECH CENTER COMPLETE		
18	11/10/2004	REFERENCE CAPTURE ON IDS		
17.7		INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
17		INFORMATION DISCLOSURE STATEMENT (IDS) FILED		
15	03/27/2006	CASE DOCKETED TO EXAMINER IN GAU		
14	03/23/2006	CLEARED BY OIPE CSR		
13	03/23/2006	CLEARED BY OIPE CSR		
12	03/23/2006	CLEARED BY OIPE CSR		
11	03/23/2006	CLEARED BY OIPE CSR		
10	03/03/2006	OATH OR DECLARATION FILED (INCLUDING SUPPLEMENTAL)		
9	11/10/2004	371 COMPLETION DATE		
8	03/13/2006	APPLICATION DISPATCHED FROM OIPE		
7	03/13/2006	NOTICE OF DO/EO ACCEPTANCE MAILED		
6	02/21/2006	ADDITIONAL APPLICATION FILING FEES		
5	02/06/2006	PRE-EXAM OFFICE ACTION WITHDRAWN		
4	111 1 / / 1 125 / / 1 11 125	NOTICE OF DO/EO MISSING REQUIREMENTS MAILED		
3	01/31/2006	PCT CLASSIFICATION		
2	10/06/2005	CORRESPONDENCE ADDRESS CHANGE		

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EXPLANATION OF PTA CALCULATION

EXPLANATION OF PTE CALCULATION

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